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Dated: 3-22-05 Signature: Maura A. Gallagher  
(Maura A. Gallagher)

Docket No.: ASZD-P01-659  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Andrew David Morley

Application No.: 10/506592

Confirmation No.: 2926

Filed: September 3, 2004

Art Unit: 1615

For: INDOLE-AMIDE DERIVATIVES AND  
THEIR USE AS GLYCOGEN  
PHOSPHORYLASE INHIBITORS

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A summary/abstract translation of the non-English language references is enclosed.

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this

The PTO did not receive the following  
listed items(s) FOR , NPL

Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. ASZD-P01-659. A duplicate copy of this paper is enclosed.

Dated: March 22, 2005

Respectfully submitted,

By   
\_\_\_\_\_  
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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/506592
				Filing Date	September 3, 2004
				First Named Inventor	Andrew David Morley
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	ASZD-P01-659

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA	US-2004/0002495-A1	01-01-2004	Philip Sher		
AB	US-3,706,810	12-19-1972	AMERICAN CYANAMID		
AC	US-4,599,198	07-08-1986	DENNIS J. HOOVER		
AD	US-4,668,769	05-26-1987	DENNIS J. HOOVER		
AE	US-4,720,503	01-19-1988	BRUCE E. WITZEL		
AF	US-4,751,231	06-14-1988	WASYL HALCZENKO		
AG	US-4,786,641	11-22-1988	SIEGFRIED GOLDMANN		
AH	US-4,794,120	12-27-1988	PHILIPPE MANOURY		
AI	US-5,863,903	01-26-1999	KARSTEN LUNDGREN		
AJ	US-5,998,463	12-07-1999	BERNARD HULIN		

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	WO-00/42213		07-20-2000	The Research Foundation of State University of New York	
BB	WO-00/47206		08-17-2000	Novo Nordisk	
BC	WO-01/05954		01-25-2001	Isis Pharmaceuticals, Inc.	
BD	WO-01/23347		04-05-2001	Novo Nordisk	
BE	WO-01/32654		05-10-2001	Societe de Conseils de Recherches et D'Applications Scientifiques	
BF	WO-01/52825		07-26-2001	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	
BG	WO-01/68055		09-20-2001	Pfizer Products Inc.	
BH	WO-01/68092		09-20-2001	Pfizer Products Inc.	
BI	WO-01/68603		09-20-2001	Bristol-Myers Squibb Co.	
BJ	WO-01/94300		12-13-2001	Aventis Pharma Deutschland	
BK	WO-01/96311		12-20-2001	Bristol-Myers Squibb Company	
BL	WO-01/96347		12-20-2001	Bristol-Myers Squibb Company	
BM	WO-02/080844		10-17-2002	Genzyme Corporation	
BN	WO-02/096864		12-05-2002	Aventis Pharma Deutschland GmbH	
BO	WO-02/098348		12-12-2002	Eli Lilly and Company	
BP	WO-02/26714		04-04-2002	Takeda Chemical Industries, Ltd.	
BQ	WO-02/34718		05-02-2002	Richter Gedeon Vegyeszeti Gyar Rt.	
BR	WO-03/037864		05-08-2003	Japan Tobacco Inc.	
BS	EP-0846464		06-10-1998	Pfizer Inc.	
BT	EP-0884050		12-16-1998	Novo Nordisk	
BU	EP-0978279		02-09-2000	Pfizer Products Inc.	
BV	EP-1088824		01-07-2004	Pfizer Products Inc.	
BW	EP-1125580		08-22-2001	Pfizer Products Inc.	
BX	EP-1134213		09-19-2001	Pfizer Inc.	
BY	EP-1136071		09-26-2001	Pfizer Products Inc.	
Examiner Signature			Date Considered		

Substitute for form 1449A/B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	2	of	3	Application Number	10/506592
				Filing Date	September 3, 2004
				First Named Inventor	Andrew David Morley
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	ASZD-P01-659

BZ	EP-1145717	05-12-2004	Pfizer Products Inc.		
BA1	EP-1149580	02-21-2001	Pfizer Products Inc.		
BB1	EP-1177791	07-27-2001	Pfizer Products Inc.		
BC1	ES-2081747	03-01-1996	Esteve Labor DR		
BD1	DE-4445968	06-27-1996	Bayer AG		
BE1	WO-93/25574	12-23-1993	Pfizer Inc.		
BF1	WO-95/24391	09-14-1995	Novo Nordisk		
BG1	WO-96/39384	12-12-1996	Pfizer, Inc.		
BH1	WO-96/39385	12-12-1996	Pfizer Inc.		
BI1	WO-97/09040	03-13-1997	Novo Nordisk		
BJ1	WO-97/31901	09-04-1997	Mikael Bols		
BK1	WO-97/45425	12-04-1997	Fujisawa Pharmaceutical Co., Ltd.		
BL1	WO-98/27108	06-25-1998	Fuji-Sawa Pharmaceutical Co., Ltd.		
BM1	WO-98/40353	09-17-1998	Novo Nordisk		
BN1	WO-98/50359	11-12-1998	Novo Nordisk		
BO1	WO-99/26659	06-03-1999	Pfizer Products Inc.		
BP1	WO-99/36393	07-22-1999	Tanabe Seiyaku Co., Ltd.		
BQ1	JP 2001 089368				
BR1	DD 200740	06-08-1983	Gewald		
BS1	EP 697403	02-21-1996	Sanofi		
BT1	JP 2001 206856	07-31-2001	Pfizer Prod. Inc.		
BU1	JP 021247565	05-14-1990	Hanawa Netsuden Kinzoku KK Toray Ind. Inc.		
BV1	JP 04179949	06-26-1992			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA	Birch, A., et al., "Novel Thienopyrrole Glycogen Phosphorylase Inhibitors: In Vitro SAR and Crystallographic Studies," Poster, AstraZeneca UK, CVGI Research, Mereside, Alderley Park, Macclesfield, Cheshire.			
	CB	Crochet, R.A., et al., "Synthesis of Substituted Thieno[2,3-b] pyrroles," Vol. 11, 143-150 (April 1974).			
	CC	Freeman, S., et al., "Effect of Glucose on Rat and Human Liver Glycogen Phosphorylase Activity and Potency of a Glycogen Phosphoylase Inhibitor," Diabetes, 52, Supp., 1470-P, A340.			
	CD	Hartman, G.D., et al., "The Synthesis of 5-Alkylaminomethylthieno[2,3-b]Pyrrole-5-Sulfonamides," Heterocycles, 29(10):1943-1949 (1989).			
	CE	Hoover, D.J., et al., "Indole-2-carboxamide Inhibitors of Human Liver Glycogen Phosphorylase," J. Med. Chem., 41:2934-2938 (1998).			
	CF	Hudson, S., et al., "The effect of a glycogen phosphorylase inhibitor upon muscle fatigue in anaesthetised rats," J. Physiol., 539:52-53 (2002).			
	CG	Jakobsen, P., et al., "Iminosugars: Potential Inhibitors of Liver Glycogen Phosphorylase,"			
Examiner Signature		Date Considered			

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				Art Unit	N/A
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Sheet	3	of	3	Attorney Docket Number	ASZD-P01-659

	Bioorganic Med. Chem., 9:733-744 (2001).			
CH	Martin, W.H., et al., "Discovery of a human liver glycogen phosphorylase inhibitor that lowers blood glucose in vivo," PNAS, 95:1776-1781 (Feb. 1998).			
CI	McCormack, J.G., et al., "Pharmacological Approaches to Inhibit Endogenous Glucose Production as a Means of Anti-diabetic Therapy," Curr. Pharmaceutical Design, 7:1451-1474 (2001).			
CJ	Oikonomakos, N.G., et al., "Allosteric inhibition of glycogen phosphorylase alpha by the potential antidiabetic drug 3-isopropyl 4-(2-chlorophenyl)-1,4-dihydro-1-ethyl-2-methyl-pyridine-3,5,6-tricarboxylate," Protein Sci., 8:1930-1945 (1999).			
CK	Rath, V.L. et al., "Activation of Human Liver Glycogen Phosphorylase by Alteration of the Secondary Structure and Packing of the Catalytic Core," Mol. Cell, 6:139-148 (July 2000).			
CL	Rosauer, K.G., et al., "Novel, 3,4-Dihydroquinolin-2(1H)-one Inhibitors of Human Glycogen Phosphorylase a," Bioorganic & Medicinal Chemistry Letters, 13:4385-4388 (2003).			
CM	Soman, G., et al. "Aromatic Compounds as Allosteric Inhibitors of Glycogen Phosphorylase beta," Biochimica et Biophysica Acta, 358:359-362 (1974).			
CN	Soman, G., et al., "The Nature of the Binding Site for Aromatic Compounds in Glycogen Phosphorylase beta," Biochem. J., 147:369-371 (1975).			
CO	Teague, J., "Mobilisation of Tissue Glycogen Following Inhibition of Glycogen Phosphorylase in fa/fa Rat," Diabetes, 53, Supp. 1, A365, 1521-P			
CP	Treadway, J.L., et al., "Glycogen phosphorlase inhibitors for treatment of type 2 diabetes mellitus," Exp. Opin. Invest. Drugs, 10(3):439-454 (2001).			
CQ	Turnbull, A., et al., "Pharmacological Inhibition of Glycogen Phosphorylase (GP) Lowers Plasma Glucose in Rat Models of Type 2 Diabetes," Diabetes, 52, Supp., 1485-P, A343.			
CR	Venkatarangan, P., et al., "Prediction of Ligand-REceptor Binding Thermodynamics by Free Energy Force Field Three-Dimensional Quantitative Structure-Activity Relationship Analysis: Applications to a Set of Glucose Analogue Inhibitors of Glycogen Phosphorylase," J. Med. Chem., 42:2169-2179 (1999).			
CS	Vertigan, H., "Impact of cell glycogen content on modulation of hepatocyte glucose metabolism by pharmacological agents," Diabetes, 47, Supp., 589, A214.			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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